DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 11, 2015

B.j.z.h.f. Panther Medical Equipment Co. Ltd.
% Chu Xiaoan
Room 1606 Bldg. 1 Jianxiang Yuan
No. 209 Bei Si Huan Zhong Road, Haidian District
Beijing, CN 102200

Re: K142577
Trade/Device Name: Panther Endo Linear Cutter Staplers With Single Use Loading Units
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: September 12, 2014
Received: September 12, 2014

Dear Mr. Chu Xiaoan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142577

Device Name
PANTHER Endo Linear Cutter Staplers with Single Use Loading Units

Indications for Use *(Describe)*
PANTHER Endo Linear Cutter Stapler with Single Use Loading Units has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transaction and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
(per 2.1 CFR 807.92)

1. Applicant

Manufacture name :	B.J.ZH.F. Panther Medical Equipment Co. Ltd.
Manufacture address:	ROM 805，Ruichuang Mansion, NO.9 Wangjing East, Beijing, 102200, China
Contact person	Ms. Liu Yu
Phone & fax numbers	8610-6970402-8039
Date prepared:	9/9/2014

2. Device Name

Trade or Proprietary Name: PANTHER Endo Linear Cutter Stapler with Single Use Loading Units

Common/Usual Name: Surgical Stapler with Implantable Staple

Classification Name: Implantable Staple

Regulation Number: 878.4750

Product Code: GDW

Classification: II

Panel: General & Plastic Surgery

3. Predicate Device

3.1 Device

Autosuture ™ ENDO GIA™ Staplers with ENDO GIA ™ Single Use Loading Units with Staple Line Reinforcement (K 080898)

3.2 Manufacture

Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien)

4. Intended Use

PANTHER Endo Linear Cutter Stapler with Single Use Loading Units has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transaction and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

5. Description of the Devices

The proposed device, PANTHER Endo Linear Cutter Staplers with Single Use Loading Units (SULU) is sterile (ETO), single-patient-use surgical instruments, which has applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

It places two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two triple-staggered rows. The Endo Linear Cutter Stapler will accommodate any of the reloading unit with staple cartridge lengths of 30mm, 45mm,

and 60mm and come in long or compact shaft lengths, and they may be reloaded and fired up to 25 times in a single procedure. The size of the staples is decided by selecting 2.0 mm, 2.5 mm, 3.5 mm, 4.0 mm or 4.8mm SULU.

The SULU has two configurations: (1) Straight SULU and (2) Articulating SULU, each of them has various specifications.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. These tests include: Physical Performance Testing, Endotoxin Testing, Package Integrity Testing, and Shelf Life Testing.

7. Substantially Equivalent (SE) Conclusion

The following table compares the proposed-device to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

.Table 1 Product Comparison Table

Features & Description		Subject Device	Predicate Device
Product Code		GDW	Same
Regulation Number:		878.4750	Same
Class		II	Same
Intend for use		PANTHER Endo Linear Cutter Stapler with Single Use Loading Units (SULU) has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transaction and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.	Same
Cutting Mechanism		Linear Knife	Same
Operation Principle		Manual	Same
Safety Mechanism		Green button for preventing from miss-firing.	Same
Staple shape		B-Shaped	Same
Closed staple height(mm)		0.75,1.0, 1.5, 2.0	Same
material	Staple	ISO 5832-2: Implants for surgery - Metallic materials - Part 2: Unalloyed titanium	Same

	Kinife	Stainless steel	Same
	Stapler	Polymeric materials, surgical grade stainless steels, adhesives, and lubricants	Very Similarly
Sterilization		EtO sterilized , SAL: 10^{-6}	Same
Packaging		PET shrink plastic tray and Tyvek ®.dialyzed paper	Same
Shelf life		36 months	Same
Biocompatibility		Cytotoxicity Compliance with ISO 10993-5	Same
		Irritation Compliance with ISO 10993-10	Same
		Sensitization Compliance with ISO 10993-10	Same

Although there is a little different from the Predicate Device, the staple line reinforcement material (the synthetic absorbable film) on the ENDO GIA TM UNIVERSAL Single Use Loading Units (SULUs), but there are no substantial differences between the PANTHER Endo Linear Cutter Stapler with Single Use Loading Units (SULU) and the predicate devices. They have the same or similar indications for use. In addition, the minor differences in the technological characteristics do not raise issues of safety and effectiveness.

8. **Conclusion**

The proposed device, Endoscopic Linear Cutting Staplers with Single Use Loading Units, is determined to be Substantially Equivalent (SE) to the predicate device. Autosuture ™ ENDO GIA™ Staplers with ENDO GIA ™ Single Use Loading Units with Staple Line Reinforcement (K 080898), in respect of safety and effectiveness.